AMENDMENTS TO THE DRAWINGS

The attached Replacement Sheet includes changes to Figure 1. Specifically, Figure 1 has been corrected by removing reference characters **24** and **26** from the drawing.

The attached New Sheet includes new Figures 5a-b and 6a-b Specifically, Figure 5a illustrates the recited feature of claim 3, wherein the emitted radiation comprises reflected radiation from the sample. Figure 5b illustrates the recited feature of claim 4, wherein the emitted radiation comprises transmitted radiation and reflected radiation from the sample. Figures 6a-b illustrate the embodiment of claim 16, wherein the pharmaceutical sample is positioned inside a blister of a blister pack.

Attachments: Replacement Sheet (Fig. 1)
New Sheet (Figs. 5a-b and 6a-b)

REMARKS

I. Petition for Extension of Time

Applicants herewith petition the Commissioner for Patents to extend the time for response to the Office Action mailed January 9, 2007 for one (1) months from April 9, 2007 to May 9, 2007. Authorization is given to charge the extension of time fee of $120.00 (37 C.F.R. §1.136 and §1.17) to Deposit Account No. 23-1703. Any deficiency or overpayment should be charged or credited to the above numbered deposit account.

II. Drawings

The drawings are objected to as failing to comply with 37 C.F.R. §1.84(p)(5) because Figure 1 includes the reference characters **24** and **26** which are not mentioned in the description. Figure 1 has been corrected by removing reference characters **24** and **26** from the drawing.

Relying on 37 C.F.R. §1.83(a), the examiner requires the recited features of claims 3, 4 and 16, respectively, to be illustrated in a drawing. In response to the objection, Applicants submit a new drawing sheet. Figure 5a illustrates the recited feature of claim 3, wherein the emitted radiation comprises reflected radiation from the sample. Figure 5b illustrates the recited feature of claim 4, wherein the emitted radiation comprises transmitted radiation and reflected radiation from the sample. Figures 6a-b illustrates the embodiment of claim 16, wherein the pharmaceutical sample is positioned inside a blister of a blister pack.

The specification has bend amended to provide the corresponding description of Figures 5a-b and 6a-b.

Applicants submit that no new matter has been introduced by any of the changes to Figure 1 or by the addition of Figures 5a-b and 6a-b. Withdrawal of objections under 37 C.F.R. §§1.83(a) and 1.84(p)(5) is requested. Formal drawings of new Figures 5a-b and 6a-b will be submitted once the draftsperson has approved the informal drawings submitted for examination purposes in response to the objections.

III. Claim Amendments

Claim 1 has been amended to incorporate the feature of claim 28 which has been canceled. As such, amended claim 1 is generally directed to a method for making a pharmaceutical sample. More specifically, amended claim 1 is directed to a method for controlling the manufacture of a pharmaceutical sample. The manufacturing process is controlled by using the detected amount of free gas within the pharmaceutical sample and correlating the generated signals corresponding to the amount of detected free gas to at least one solid state property of pharmaceutical sample. Advantageously, by following the steps of the claimed method, it is possible to manufacture pharmaceutical samples having pre-determined properties, e.g., hardness, distintegrability, dissolvability, etc.

Applicants submit that the claim amendments are fully supported by the original specification and do not introduce any new matter.

IV. Claim Rejections – 35 U.S.C. §101

Claims 1-32 are rejected under 35 U.S.C. §101 as allegedly being directed to non-statutory subject matter. The Examiner alleges that the claims fail to include the transformation from one physical state to another without a tangible result being claimed. Specifically, the Examiner states that the recited step of correlating the analyzed amount of free gas is not linked to a useful or practical application.

Applicants respectfully submit that amended claim 1 renders moot the §101 rejection. The tangible result of the claimed invention is a pharmaceutical sample that is prepared by a controlled method for making and obtaining a sample having certain predetermined properties. The transformation is from an earlier stage of the manufacturing process to a subsequent stage when the pharmaceutical sample is determined to have the desired characteristics. In accordance with the method of amended claim 1, the recited step of correlating the detected amount of free gas is expressly linked to the step of controlling the manufacture of pharmaceutical samples having certain predetermined properties.

For all of the foregoing reasons, withdrawal of the §101 rejection is requested.

V. Claim Rejections – 35 U.S.C. §103(a)

Claim 1 is the only independent claim. Claim 1 was amended to incorporate the feature of claim 28 which has been canceled. As set forth in Paragraph 9 at pages 9-10 of the Office Action, claim 28 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Sjöholm, M. et al., "Analysis of gas dispersed in scattering media", Optical Society of America (2001), Vol. 26, No. 1 ("Sjöholm") in view of EP 0 110 502 ("Mayer") and further in view of WO 00/03229 ("Folestad").

All of the remaining claims 2-27 and 29-32 are either directly or indirectly dependent on claim 1. Therefore, but for the §103 rejection of claim 28, amended claim 1 renders moot the §103 rejection of claims 1-27 and 29-32 as set forth in Office Action in Paragraphs 6-11 at pages 5-12 of the Office Action.

A. Sjöholm and Mayer

Claims 1-3, 5-15, 17-19, 22, 23 and 29-32 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Sjöholm and Mayer.

Applicants submit that the rejection is moot in view of amended claim 1 which incorporates the feature of claim 28. Claim 28 was not rejected in view of the combination of Sjöholm and Mayer. Each of the rejected claims 2, 3, 5-15, 17-19, 22, 23 and 29-32 is either directly or indirectly dependent on claim 1. Withdrawal of the rejection is requested.

B. Sjöholm, Mayer and Egelberg

Claim 4 is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Sjöholm, Mayer and further in view of EP 0 959 342 ("Egelberg").

Applicants submit that the rejection is moot in view of amended claim 1 which incorporates the feature of claim 28. Claim 28 was not rejected in view of the combination of Sjöholm, Mayer and Egelberg. Claim 4 is directly dependent on claim 1. Withdrawal of the rejection is requested.

C. Sjöholm, Mayer and Egelberg

Claim 16 is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Sjöholm, Mayer and further in view of US 6,667,802 to Faus et al. ("Faus").

Applicants submit that the rejection is moot in view of amended claim 1 which incorporates the feature of claim 28. Claim 28 was not rejected in view of the combination of Sjöholm, Mayer and Egelberg. Claim 16 is indirectly dependent on claim 1. Withdrawal of the rejection is requested.

D. Sjöholm, Mayer and Folestad

Claims 20, 21 and 28 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Sjöholm, Mayer and further in view of Folestad.

1. Sjöholm

Sjöholm relates to a process for detecting and characterizing free gas which is dispersed in scattering media. The authors state that the measurements have been limited to the extraction of emitted gas from plants, fruits and insects. The Examiner has acknowledged that Sjöholm. does not discuss the application of the method to the detection of free gas in a pharmaceutical sample.

The authors of the primary reference and the Examiner are in agreement: Sjöholm is directed to a method for detecting free gas in a specific and limited class of materials, i.e., scattering media, e.g., an apple. Therefore, in the absence of impermissible hindsight, Applicants submit that there is no suggestion that Sjöholm's technique of detecting gas dispersed in a scattering media could be used or would be useful in the controlled manufacture of a pharmaceutical sample having predetermined characteristics.

2. Mayer

Mayer relates to the production of foam capsules. It is disclosed that it is possible to obtain white opaque film-forming mixtures by the inclusion of suitable gases such as air, oxygen, nitrogen, carbon dioxide and argon into natural transparent gelatin solutions (p. 2 at lines 52-56).

At page 6 of the Office Action, the Examiner alleges that it would have been obvious to use the method of Sjöholm to obtain a quick non-destructive detection of the free gas in a pharmaceutical sample such as disclosed by Mayer.

Applicants respectfully disagree and ask: where is the motivation to apply Sjöholm's technique for the detection of free gas to Mayer when Mayer knows precisely the gas content that is introduced into the aqueous gelatin solution (See, p. 3, lines 37-38; Example 1; and claim 4).

Furthermore, Sjöholm expressly states that his measurements have been limited to the extraction of emitted gas from plants, fruits and insects. As such, there is no suggestion that Sjöholm's technique for detecting dispersed gas would be useful with ***any*** material or substance containing free gas that is distributed throughout the material. This lack of suggestion does not change simply because Mayer discloses a foam capsule having a quantifiable gas content. In other words, the Examiner cannot combine Sjöholm with any secondary reference simply because the secondary reference discloses a material having a content of a dispersed gas.

There must be some suggestion for combining Sjöholm's technique with Mayer for detecting the free gas dispersed in the foam capsule. Not only does Mayer know that gas is present in the foam capsule, but Mayer also knows precisely the amount of gas that is introduced into the aqueous gelatin solution, e.g., 23% in Example 1. So why does Mayer need the gas detection method of Sjöholm?

3. Folestad

Folestad relates to a method for controlling the process of manufacturing a coating of a pharmaceutical product. In general, the process comprises the step of performing a spectrometric measurement ***directly*** on the coating and comparing that information to a predetermined corresponding model parameter to extract information relating to the quality of the coating.

In contrast to the direct measurement technique employed by Folestad, the claimed method uses an ***indirect*** measurement. Specifically, the claimed method indirectly obtains information regarding the solid state parameters of a pharmaceutical sample by analyzing the amount of free gas within the sample, i.e., it is the amount of free gas in the sample that

generates a signal due to irradiation. The generated signal is then correlated to a solid state parameter of the sample. This is just the opposite to Folestad which discloses that the quality of the coating should be measured ***directly***. As such, Folestad does not suggest the claimed invention.

In fact, it appears that Folestad teaches away from any type of indirect measurement. At page 3, lines 2-24, Folestad states that indirect methods for controlling the manufacture of a coating, e.g., dissolution, storage stability, etc., are slow and imprecise. It is noteworthy that Mayer uses such an indirect measurement, i.e., disintegration (See Example 1), to evaluate properties of the foam capsule. Applicants submit, therefore, that Mayer and Folestad are incompatible (indirect vs. direct measurement). Accordingly, there is no motivation or suggestion to combine Mayer and Folestad.

4. Summary

Sjöholm discloses a technique for detecting gas which is dispersed in scattering media. Sjöholm does not discuss the application of the method to the detection of free gas in a pharmaceutical sample. Furthermore, there is no disclosure or suggestion that Sjöholm's technique could be used or would be useful in the controlled manufacture of a pharmaceutical sample having predetermined characteristics.

Mayer disclose the preparation of a foam capsule by introducing a known amount of gas to an aqueous gelatin solution. Therefore, the application of Sjöholm's technique to Mayer's foam capsule would superfluous in view of the known gas content of the foam capsule.

The ***direct*** measurement technique of Folestad teaches away from the claimed method of obtaining ***indirect*** measurements to control the manufacture of a pharmaceutical sample. Furthermore, the ***direct*** measurement technique of Folestad is incompatible with the ***indirect*** measurement techniques employed by Mayer. Accordingly, there is no motivation to combine Mayer and Folestad.

For all of the foregoing reasons, Applicants submit that a *prima facie* case of obviousness has not been established. None of Sjöholm, Mayer and Folestad, whether taken alone or in combination, suggests the claimed invention as defined by amended claim 1. Withdrawal of the §103 rejection based on the combination of Sjöholm, Mayer and Folestad is requested.

E. Sjöholm, Mayer and Bachuer

Claim 24 is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Sjöholm, Mayer and further in view of US 2003/0111607 ("Bachuer").

Applicants submit that the rejection is moot in view of amended claim 1 which incorporates the feature of claim 28. Claim 28 was not rejected in view of the combination of Sjöholm, Mayer and Bachuer. Claim 24 is directly dependent on claim 1. Withdrawal of the rejection is requested.

F. Sjöholm, Mayer and Folestad '02

Claims 25-27 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Sjöholm, Mayer and further in view of US 2002/0125434 ("Folestad '02").

Applicants submit that the rejection is moot in view of amended claim 1 which incorporates the feature of claim 28. Claim 28 was not rejected in view of the combination of Sjöholm, Mayer and Folestad '02. Claims 25-27 are directly dependent on claim 1. Withdrawal of the rejection is requested.

Applicants submit that the prior art of record but not relied upon does not disclose or suggest the claimed invention: US 4,800,279 to Hieftje et al. and US 5,679,954 to Soloman.

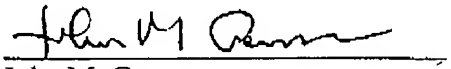
CONCLUSION

Applicants have made a good faith attempt to respond to the Office Action. It is respectfully submitted that claims 1-27 and 29-32 are in condition for allowance, which action is earnestly solicited.

Any fees due in connection with this response should be charged to Deposit Account No. 23-1703.

Dated: April 11, 2007

Respectfully submitted,



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